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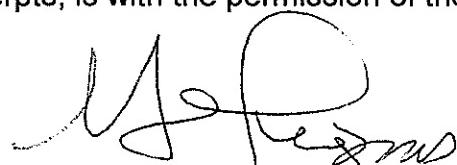
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**IN-VITRO MEASUREMENT OF INSERTION TORQUE, REMOVAL
TORQUE AND RESONANCE FREQUENCY ANALYSIS OF IMPLANTS
PLACED INTO SIMULATED BONY DEFECTS.**

BY
GEORGE ANTHONY QUIROA
A THESIS

Submitted in partial fulfillment of the requirements
for the degree of Master of Science in the
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2014

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LIST OF ABBREVIATIONS

cpTi - commercially pure Titanium

PIS- Primary implant stability

CP - commercially pure

N-cm - Newton centimeters

RFA - Resonance frequency analysis

ISQ - Implant stability quotient

ITQ - Insertion torque

RTQ - Removal torque

MPa – Megapascal

BIC – Bone implant contact

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ABSTRACT

Adequate Primary Implant Stability is the most important factor in predicting dental implant osseointegration and long-term success. Measurements of insertion torque, removal torque, and resonance frequency analysis are parameters used to evaluate primary and secondary implant stability.

Aims: To evaluate the effects of simulated bony defects placed adjacent to dental implants have on insertion torque, removal torque and resonance frequency analysis.

Methods: A total of 45 titanium dental implants with the measurements of 3.75 x 7 mm were placed into artificial synthetic bone (Polyurethane Foam Blocks). A control block of 15 implants without defects were compared to implants with adjacent simulated bony defects. Two additional and separate blocks of 15 implants were placed with adjacent defects with the dimensions of 3.5mm x 2mm in block 2 and 7.0mm x 2mm in block 3. Stability measurements using Resonance Frequency Analysis (RFA), Insertion Torque (ITQ), and Removal Torque (RTQ) were performed and the values compared.

Results: Compared to the control, the 3.5mm defect showed no statistically significant effect on implant stability as measured by insertion torque and removal torque. In contrast, the 7.0mm defect had a significant effect, reducing ITQ/ stability by 26.3% and a 24.7% reduction in RTQ/ stability when compared to the control group that had no defect. The RFA showed no significant relationship to bone defect. However, within both defect groups, but not the control the, RFA-B (buccal) showed a small decrease relative to RFA-M (mesial).

Conclusions: Based on the resulting measurements, the control group and the 3.5mm defect group had similar primary implant stability values for insertion torque (ITQ), removal torque (RTQ) and resonance frequency analysis (RFA). However, the 7.0mm defects reflected a reduction in primary implant stability as reflected by Insertion torque (ITQ) and removal torque (RTQ). The RFA did not reflect reduced stability for any of the test groups. The insertion torque and removal torque measurements show that only the 7mm defect group reflected reduced implant stability. The 3.5mm defect group did not show reduced stability based on any stability measurements.

INTRODUCTION

In the field of dentistry replacing missing teeth has been a service provided for many dental patients. In addition to fixed bridges and removable dentures, dental implants have become increasingly popular and are a good treatment option for the replacement of missing teeth. A dental implant (known currently as an endosseous root form implant or fixture) is a surgical component that interfaces with the bone of the jaws to support a dental prosthesis such as a crown, bridge, denture or used as an orthodontic anchor. Most implants connect to other components in order to function. A common component is an abutment that simulates the coronal portion of a natural tooth that can provide the connection to a dental prosthesis.

A 2007 study on implant survival of 192 fixtures found only four failures for a cumulative survival rate of 97.9 % (Blanes, Bernard 2007). The most important factor related to implant survival/success is the primary stability, which is related to the mechanical union between the implant and bone (Simunek 2012). The degree of primary implant stability is reflected by the local bone quality and quantity, surgical technique and type of implant used. Primary implant stability is the implant stability at the time of placement and can be measured using insertion torque and resonance frequency analysis. These measuring tools will be defined and used in this study.

History of Implants

Endosseous implants have been discovered by archaeologist's dating back to 600 AD and 1350 years before Per- Ingvar Branemark, known as the "Father of Modern Implantology", started working with and developing titanium implants. Archaeologist's discovered mandibles containing pieces of tooth shaped sea shells within anterior tooth

sockets (Driskell, 1987). At least 4000 years ago the Chinese used bamboo for dental implants. In 1685, in the first modern textbook on dentistry (Operator for the teeth), Charles Allen suggested using teeth from dogs, sheep, and baboons for implantation. However, infection and disease transmission was a recognized concern (Torabinejad, Goodacre, Sabati 2014). Later in 1807, J. Maggiolo a French dentist developed a one stage gold implant that was placed into fresh extraction sockets; however, pain, inflammation and infection resulted (Torabinejad, Goodacre, Sabati 2014). The early implants failed to produce long-term clinically successful outcomes. However, in the 1950's an important discovery was made pertaining to bone and metal adherence.

Initial observations of metal to bone adherence were noted in a 1950 Cambridge university study conducted on circulation in bone marrow using titanium chambered tubes placed in rabbit ears. Two years later in 1952, Branemark decided to use the titanium tube design for his study on bone healing and regeneration. Branemark placed and fixed titanium tube optic chambers into rabbit tibias and fibulas. He later found them to be embedded into the bone after several months of healing. He expanded on this original study and developed intraoral dental implants that supported full-arch dental prosthesis or dentures.

Dr. Branemark is credited for the term osseointegration which was originally defined as a direct structural and functional connection between ordered living bone and the surface of a load-bearing implant (Branmark, R; Branmark, P-I 2001). Currently, an implant is regarded as osseointegrated when there is no progressive movement between the implant and bone with which it has direct contact (Mavrogenis, A.F.; Dimitriou, R. 2009). Prior to, and after Branemark, many implant attempts were

unsuccessful due to the formation of a fibrous encapsulation around the implant and soft tissue. This type of healing and encapsulation led to inflammation, infection, mobility and failure of the implants. Research and practice have eliminated most of the common problems causing implant failure and today with improved designs and surgical techniques, implants have success rates often in the upper 90% range.

In modern dental history, there have been three major types of dental implants used: Endosseous, Subperiosteal, and Transmandibular type dental implants. The Subperiosteal and Transmandibular are rarely used today in clinical practice. The Transmandibular implant was used to secure the prosthesis by way of intrabony fixation. Screws were placed in the inferior border of the mandible and passing through and within the bone to a connection within the denture (Albrektsson and Sennerby 1991). The Subperiosteal implants were popular in the 1980's and 1990's and were placed below the periosteum on top of the bony ridge. Many of these Subperiosteal implants failed due to post-operative infection. The blade and pin form implants were the first endosseous type implants placed. These blade and pin type endosseous implants failed due to surgical and implant design flaws that created a fibrous scar formation that inhibited integration into the bone (Albrektsson and Sennerby 1991).

In Sweden, osseointegrated screw type implants became acceptable in 1977 and then internationally by 1982. This acceptance came about due to long term positive clinical results. In the 1980s, Professor Zarb of the University of Toronto held the Toronto Conference on Osseointegration. At this conference, Bränemark presented the results of his research and subsequent clinical practice of over 30 years. Bränemark recommended that, after implantation, the fixture should remain in bone isolated from

any kind of external force and be allowed to osseointegrate for four to six months. With this Conference as a turning point, the Bränemark introduction of osseointegration and its application in treating edentulous patients spread over North America (Ring M.E. 1995).

Root formed and screw type implants are used today with a variety of designs and surface textures aimed at improving osseointegration. Currently, surface modifications of titanium implants include acid etching, sand blasting and plasma sprayed techniques to create a micro-roughness surface in order to improve healing and enhance bone formation around the implants (Strnad, Urban 2008). Also, bioactive agents represent a growing area of research in implant dentistry. Bioactive agents such as bone morphogenetic proteins, growth factors, type one collagen, and fluoride, among others may be applied to coat the titanium implant surface. These agents are used in an attempt to gain faster osseointegration (Gustavo, Kelly 2009).

Osseointegration

A dental implant is regarded as osseointegrated when there is no progressive relative movement between the implant and the bone with which it has contact (Branmark, R; Branmark, P-I 2001). With osseointegration, there is an anchorage in which non-vital components can be reliably incorporated into living bone and this anchorage can continue under normal loading conditions (Branmark, R; Branmark, P-I 2001). This relationship is a combination of implant and bone interlocking and direct surface adhesion and is considered critical for implant bone success. (Meredith 1997).

Previous studies showed that an important factor in osseointegration is bone quality. Bone quality relates to the differences in thickness of cortical and trabecular bone. Lekholm & Zarb (1985) classified the quality of bone within the jawbones of the maxilla and the mandible into four Types: Type 1 bone is composed of homogenous compact bone and is considered the hardest and densest of all types. This bone type is found in the anterior mandibular region of jaws. Type 2 bone is composed of a thick outer layer of compact bone surrounding a core of dense trabecular bone. It is generally found in the anterior maxilla. Type 3 bone consists of a thin layer of compact bone encompassing a dense layer of trabecular bone and can be found in the posterior mandible. Type 4 bone consists of a thin layer of cortical bone surrounding a core of low density trabecular bone and is considered the weakest type of bone of the jaws. It is the least dense bone found in the oral cavity, and is generally found in the posterior maxilla. Both jaws tend to decrease in their cortical thickness and increase in their trabecular porosity as they move posteriorly (Lekholm U, 1985).

Osseointegration and implant success is related to the type of bone, implant characteristics and the surgical techniques used (Huang, Chiu et al. 2003); (Pattijn 2006). When an implant is placed into bone, the bone-implant interface becomes a living interface that consists of mechanical and biological properties that are continuously adapting over time (Brunski 1992). A study was completed by Perez in 2007 that evaluated the time evolution of the osseointegration process for a dental implant with regards to time and mechanical function. With this in mind, a computer 3D model of a rabbit tibia was created and a finite element analysis was performed using numerous algorithms (functions). This model represented the dental implant embedded

within the tibia and was able to simulate the mechanical effects on the osseointegration process at the bone-implant interface. The model was able to successfully relate the resonance frequency, which is a measurement used to determine implant stiffness and stability, of the system with osseointegration degree at the bone implant interface and in turn the long term stability of the implant (Moreo et al., 2007). Based on time and function, it was shown that after 7-8 weeks of initial implant placement the dental implant was completely osseointegrated and stability can be fully achieved. (Perez 2007).

Implant Stability

Implant stability (Total Stability) is divided into two stages: primary stability (implant stability during initial placement) and secondary implant stability (implant stability after healing i.e. osseointegration). In general, primary implant stability has been proven to be mechanical in nature whereas secondary implant stability is a result of biologic events. In secondary implant stability, both biologic and mechanical components are involved. At the time of placement, primary implant stability is based on a mechanical component alone (Simunek, Kopecka et al. 2012).

Interestingly, during the healing period of an implant, mechanical stability decreases whereas the biologic healing increases with progression of osseointegration. A 3 to 4 week period between the initial implant placement and osseointegration is considered the time of least stability for an implant. This is due to the skeletal to implantation-related injury and key histological events as related to the host response after insertion and mechanical fixation of cementless dental implants. The histological events include hematoma formation, and mesenchymal tissue development, woven bone formation

through the intramembranous pathway, and lamellar bone formation on the spicules of woven bone (Mavrogenis; Dimitriou 2007). The first biological component to come into contact with an endosseous implant is blood. Red blood cells, platelets, inflammatory cells such as polymorphonuclear granulocytes and monocytes, accumulate around the implant-bone interface causing decreased mechanical stability (Mavrogenis; Dimitriou 2007). In other words bone remodeling occurs during this period reducing the bone implant contact (BIC) and stiffness. It is critical during this time not to apply forces on the implant. The final stability relies entirely on biologic healing for osseointegration to be complete (Simunek, Kopecka et al 2012). However, for secondary stability/osseointegration to take place, primary implant stability must be established at the time of implant placement (Turkyilmaz, Company 2011).

Primary Implant Stability

In order for an implant to have good primary stability it is recommended the final insertion torque value of 30 N-cm or higher be established in order to prevent micromotion (Thibaut 2009). Also a torque range of 30 N-cm to 100 N-cm is recommended to reduce the risk of micromotion (Trisi 2009). This torque can be measured by using a hand held gauge that is placed on the implant fixture and turned in a clockwise direction or by using a hand-piece unit that provides torque measurements. Furthermore, it is suggested that the success of the implant is a function of a critical micromotion threshold, and based on previous studies this threshold should not exceed 100 um at the implant interface (Trisi P, 2009). Micromotion causes excessive bone resorption that can occur at the interface of the implant due to a lack of implant stability.

Bone resorption can occur even with small loads and a displacement of only a few micrometers at the bone implant interface (Ganz, 1975; Perren, 2002). When high insertion torque and primary stability are established, we see that micromotion is reduced allowing for bone remodeling and subsequent reduction in the peri-implant fibrosis.

When primary stability is not established after initial placement, the implant can move allowing a fibrous connective tissue capsule to develop around the implant (Brunski 1988). This fibrous connective tissue may prevent osseointegration and increase the chance of implant failure (Pilliar RM, 1986; Szmukler-Moncler S, 1998). Primary stability can be influenced by the type (I –IV) and quantity of bone the implant was placed into. Establishing primary stability in a patient with a Lekholm and Zarb type III or IV (least dense) bone classification may be a challenge because of the lower density and reduced quantity of bone available as an implant bed (Blahout; Hienz, 2007). This might be seen in a patient who has been edentulous for a long time and resorption has occurred (Lekholm; Zarb 1985). An increase in bone density is shown to significantly improve the primary implant stability (Thibaut 2009).

In addition to bone quality and quantity the geometry of an implant can influence primary stability. In a previous study, it was shown that longer and wider implants placed in hard and soft bone, reflected greater primary implant stability based on resonance frequency analysis (Lachmann; Laval). Also, implant surface alteration and technology has improved the rate of bone formation on the surface that can improve secondary stability. Rough implant surfaces appear to promote better adhesion of bone fragments than machined smooth implant surfaces, and may result in increased bone

formation (Shalabi MM. Wolke JGC, Jansen JA). The goal is to have an adequate insertion torque reflecting adequate primary stability to prevent micromotion. This will lead to secondary implant stability and healing.

Secondary Implant Stability

Secondary stability represents an enhancement of stability from peri-implant bone formation through gradual bone remodeling and osteoconduction, with the possibility of new bone formation around the implant (Strnad; Urban 2008). The degree of implant stability can also depend on the condition of the surrounding tissues, for example the type of local bone the implant is placed in or patient history of periodontal disease. A secure primary stability may lead to a predictable secondary stability and eventual implant osseointegration (Simunek; Kopecka 2012). The amount of micromotion at the bone-implant interface during the initial healing process is the most important factor in developing secondary stability (Strnad; Urban, 2008). When the initial healing process is complete, the mechanical stability is replaced by biological stability.

Measuring Implant Stability

Measuring implant stability initially and over time is important in monitoring and managing success. There are three main tools currently available tools used for measuring stability in implants. Two clinical tools are insertion torque measurements and resonance frequency analysis measurements with the third being removal torque which is only used in non-clinical in-vitro studies.

Insertion Torque

The insertion torque was measured only by the removal torque machine equipment during the placement of the implants and corresponds to a combination of the cutting friction of the tip of the implant in the bone, and the friction between the implant and the osteotomy hole in bone (Degidi; Daprise 2010). If the osteotomy hole is narrow or the bone quality is high (dense bone) the torque will reflect a higher value (Trisi; Carlesi 2010). Friberg and associates demonstrated that insertion torque was related BIC and radiologically assessed bone density and was not dependent on angulation, pressure, or threading (Al-Nawas; Wagner 2006).

Torque can also be determined by a current drawn from an electric motor while cutting a thread in bone (Johansson P, 1994) when using a handpiece with a torque driver built in it. The resistance to cutting has been correlated to bone quality, and higher values are found in the mandible than in the maxilla (1994; Friberg B, 1995a; b). Greater values were also found in the incisor areas compared to the premolar areas which is related to increased bone density in that specific area (1994; Friberg B, 1995a; b). The final insertion torque established can give information which may be helpful in determining optimal healing. Micromotion may be prevented when a final insertion torque of 30 N-cm or higher is established (Trisi P, 2009).

While sufficient torque is important for primary stability and prevention of micromotion, excessive torque can cause problems. An over tightened fixture can cause continuous compression to the surrounding bone and implant threads which can lead to bone resorption through the process of pressure necrosis (Ueda et al; 1991).

Removal Torque

The removal torque testing technique is a process by which a removal torque is applied to an implant in the reverse direction of insertion and is related to friction created when removing the implant (Meredith, 1997). Removal torque up to a level of 20 N/cm is considered an adequate value for osseointegration (Makary 2012; Sullivan 1996). If an implant resists a reverse torque up to this value it is considered to be osseointegrated, but if the implant unscrews or fails to resist the torque at the osseointegration phase, then it is considered a failure (Meredith, 1997). However an increased reverse torque is considered to be a destructive measure of stability due to the direct application of shear forces to the implant-bone interface (Meredith, 1997). Studies have reported that reverse torque results in irreversible plastic deformation and damage, even at low levels (R, 1996). For this reason, removal torque is not used to clinically test implant stability after implants are placed in humans. As in this In-vitro study, removal torque is mainly used in non-clinical settings for testing primary implant stability.

Resonance Frequency Analysis

The resonance frequency analysis is a non-invasive implant stability measurement technique designed to detect changes in implant stiffness that can be monitored and measured during the healing process (Meredith N, 1996). The Implant Stability Quotient (ISQ) is the measurement scale used in resonance frequency analysis (RFA). The ISQ maps the frequencies on a scale of 1-100 ISQ. The RFA meter by Osstell ISQ (Osstell, Gothenburg, Sweden) (Figure 1) procedure uses a SmartPeg (Figure 2) attached to the

implant by a screw that is stimulated magnetically by a hand held probe. The hand held probe does not touch or connect to the implant during the stimulation. The magnetic stimulation causes the SmartPeg to resonate with certain frequencies depending on the stability/stiffness of the implant.

Studies have shown that an ISQ of 60 to 70 and above demonstrates sufficient implant stability. Dental implants are suitable for early loading if the measured ISQ is 65 to 70 and suitable for immediate loading when ISQ values are greater than 70 (Sennerby, 2013). Implants below ISQ 60 may be questionable and prone to failure (Sennerby, 2013). However, these ISQ values vary depending on the location of implant placement and the density of bone. ISQ values of 50 to 60 are seen in softer bone (maxilla) whereas ISQ values of 60 to 80 are seen in denser bone (mandible) (Sennerby, Meredith 2000).

Resonance frequency analysis (RFA)/ISQ measurements and final insertion torque numbers are used clinically to determine primary and secondary implant stability. Initial Primary stability measurements are critical when placing an implant directly into the socket immediately after extraction.

Immediate implants

The immediate placement of dental implants into fresh extraction sockets has been of increasing interest. Short-term survival rates of immediate and delayed implants appear to be similar (Chen; Wilson 2004). In addition, the survival rates of immediate and delayed implants appear to be comparable to the implant placed conventionally in healed alveolar ridges (Chen; Wilson 2004). Placing an implant into an extraction socket

is similar to placing the implant into a large bony defect with significantly less BIC. This is considered a disadvantage and may create a challenge for the provider in establishing primary implant stability for further healing. However, the majority of studies reported that peri-implant defects associated with immediate implants healed with significant bone fill, no matter what placement protocol or augmentation method was used on ridges prior to implant placement (Chen; Wilson 2004). Also, there are many advantages of immediately placing implants into extraction sockets, such as fewer surgical procedures, the elimination of a waiting period for socket healing, lowered cost and shortened edentulous time period (Barzilay 1993).

There are three types of bone interface classifications used when placing immediate implants (Barzilay 1993). Type I bone interface is ideal in which the implant is completely surrounded by bone along its periphery allowing for adequate stability. This can be seen when small extraction sites exist and larger implants are placed deep into the socket beyond the apex. Type II is a situation where the coronal aspect of the implant has space between it and the bone while the apical portion is secured and in contact with the bone. A type III situation exists when there is a defect/space present around the majority of the surface of an implant (Barzilay 1993). When a type III situation is present there is less BIC bone implant contact leading to reduced stability. This space left between the implant and bone following immediate placement is termed Jumping Distance (Wilson, IJOMI, 1998; Chen 2004).

The excessive jumping distance can cause decreased BIC that sets up a condition favorable for micromotion. When this occurs, it is recommended to extend the implant 3-

5 mm beyond the extraction socket apex to gain adequate BIC and establish good primary implant stability (Penarrocha, Uribe 2004).

Limiting micromovement is vital in achieving osseointegration. The latest trend and challenge with dental implants are the immediate/early loading protocols for immediate implants, as discussed. In addition to Type II or III extraction sockets, periodontal defects can be present on teeth planned for immediate implants, or peri-implant defects can occur, which could, in turn, reduce implant stability, either at placement or during function. Therefore, it is crucial to be able to both accurately predict primary implant stability and to monitor the implants stability during healing (Turkyilmaz; Sennerby 2008).

During immediate implant placement it would be clinically valuable to know at what size and point a defect would significantly affect stability such that it would compromise implant success. With the use of insertion torque (ITQ), removal torque (RTQ), and resonance frequency analysis (RFA), it may be possible to accurately predict adequate primary stability or reduced primary stability based on defect depth (Turkyilmaz; Sennerby 2008). This study hopes to determine at what point modern measuring techniques can verify a significant reduction in implant stability given specific sized peri-implant defects.

SPECIFIC AIMS/SIGNIFICANCE

Purpose

The primary objective of this study is to evaluate the effects of simulated peri-implant bony defects have on measurements of insertion torque, removal torque, and resonance frequency analysis. Secondarily, to evaluate if these measurements can detect a change in bone implant contact (BIC).

Hypothesis

It was hypothesized that measures of Insertion torque, removal torque, and resonance frequency analysis parameters would decline with defect depths and reduced implant bone contact.

Specific Aims

The goal this study is to determine if the simulated bony defects cause a reduction in ISQ values based on Resonance Frequency Analysis (RFA), Insertion Torque, and Removal Torque values. The bony defects simulate a similar clinical situation to immediate implant placement where there is a potential reduction in bone implant contact (BIC) contact within an extraction socket. This study hopes to establish a better understanding of the relationship between resonance frequency analysis, insertion torque and removal torque to bone loss/defects adjacent to implants.

MATERIALS AND METHODS

Overview

In this study a total of 45 implants with the dimensions of 3.75 x7 mm were placed into artificial synthetic bone. First, a control group of 15 implants were placed without defects (Figure 3). Then 15 implants were placed with an adjacent defect at depths of 3.5mm (Figure 4) and 15 implants were placed with an adjacent defect at depths of 7mm (Figure 5). All defect widths were 2mm wide, which were created by a 2mm twist drill. Measurements of ITQ, RFA and RTQ were made and evaluated. A comparison and evaluation was made of the stability measurements as it relates to the 3.5mm and 7mm depth increase. The independent variables are defect depths and widths adjacent to the implants with the dependent variables being the outcomes of RFA, ITQ and RTQ and how they relate to increased defect depths.

Implant Beds

Artificial Bone is made of solid ridged polyurethane foam that is used as an alternative test medium for human cancellous bone (Shim; Boheme 2012). Polyurethane foam blocks provide a consistent and uniform material with properties in the range of human cancellous bone. Polyurethane blocks mimic the human bone properties and are the standard material used in the mechanical testing with orthopedic implants (Shim; Boheme 2012). Four 60cm x 20cm x 20cm polyurethane foam test blocks were purchased from SAWBONES, a division of Pacific Research Laboratories, Inc. and were reduced in size to 18cm (long) x 4cm (wide) x 4cm (tall) allowing for the placement of 15 implants per block. A total of 4 blocks were used for a total number of

45 implants. One block was used to repeat two implant placements in the 7.0mm defect group. These polyurethane blocks represent type III bone without a cortical plate. SAWBONES do come with an epoxy outer sheet that simulates cortical bone but these were not used in this study due to budget constraints.

Implants

The Implant size used in this study was a 3.75 x 7mm (Figure 7) commercially pure titanium Branemark implant manufactured by Nobel Biocare. All implants placed were placed and removed by the same Removal Torque Machine at a rotation of .08 rotations /second.

Drill Types and Sizes

Drill types are made by both Nobel Biocare and Salvin companies consisting of a 2mm round guide drill (Nobel), 2mm twisted drill (Nobel), 2.4/2.8 x 7-15mm (Nobel) and a 3.5mm x 7mm twisted drill (Slavin) (Figure 9).

Drilling Sequence

Osteotomies were created using a graduated preparation model as follows: A 2mm round guide drill was used to start the osteotomy. Following the round bur was a 2mm twisted drill to a 7 mm depth. The next drill size used was a 2.4/2.8 x 7-15 mm twisted to a 7 mm depth. The last drill size used for the 3.75 mm diameter implant was the 3.5 mm twisted drill to a 7 mm depth. The last drill size used when creating the osteotomies was determined based on the diameter of the implant size being placed in the osteotomies. For every implant that was placed, the osteotomy protocol for that implant, included a

final drill size of 0.25 mm smaller than the implant size which is similar to the protocol for implant placement into real bone.

During every drill size used air was blown on the preparations to clear debris. One block at a time went through this sequence to completion and measurements were made before the next block was prepared. In addition Loupes were worn with a head light to make every effort in making consistent osteotomy preps.

Drill sequence osteotomies	Control No defects	Block 2 3.5 mm defects	Block 3 7.0 mm defects
1. 2mm round guide drill	yes	yes	yes
2. 2mm twisted drill	yes	yes	yes
3. 2.4/2.8 x 7-15 twisted	yes	yes	yes
4. 3.5mm twisted drill	yes	yes	yes
5. 2mm twisted drill for Defect preps	no	yes	yes

Table 1. Drills (figure 13) and drilling sequence for osteotomy preparations prior to implant placement.

STABILITY MEASUREMENTS

ITQ/RTQ

The Removal Torque Measuring Machine developed and manufactured by IM-Teknik Development AB (Figure 10) was used to quantify the Insertion torque (ITQ), and Removal torque (RTQ) for each implant. The RTQ machine uses a custom software program developed by National Instruments LabView. The advantage of this machine was that it allowed for a continuous view of torque values in actual time and showed a graph on the computer screen with increasing or decreasing values in amplitude and time in an x and y representation. All of the implants were inserted and removed using the RTQ machine.

Each of the 3 blocks, control and the 2 different defect groups was taken through the complete study protocol before moving to the next block. The implants were reversed for 1 full turn to obtain RTQ. The RTQ software provides information on maximum torque for each implant, time in seconds it took to place the implant, and the angle of rotation for each implant placed.

RFA

The Resonance Frequency Analysis (RFA) data was collected using the Osstell ISQ implant stability meter (Figure 1). A SmartPeg (Figure 2) was attached to each implant and screwed in place per manufacturer's instructions. Once the SmartPeg was attached, the hand-held probe of the Osstell ISQ machine was held perpendicular to the SmartPeg and two readings were captured with the probe, one on the facial/buccal surface of the implant and on the mesial surface of the implant.

STATISTICAL ANALYSIS

Overview

Multiple (4) ANOVAs for each dependent variable was conducted which required an adjustment to the alpha using Bonferroni correction. This adjustment was conducted to reduce the odds of getting a false rejection of the null hypothesis which would be considered as a type 1 error. For this study, in order for the ANOVA test to be considered significant, the p value had to come out below 0.0125 (not 0.05), to be equivalent to 0.05 over all four tests. In addition, the Browne-Forsyth and Bartlett's test were conducted in order to establish equal variance for ANOVA testing. Also, the post hoc Tukey's tests were conducted to establish a confidence of a real difference between groups.

Independent variable(s):

The independent variable in this study was defect depth with three levels of severity: 0mm, 3.5mm, and 7mm.

Dependent variables:

There were three dependent variables: insertion torque (ITQ; units of N-cm); removal torque (RTQ; units of N-cm); and resonance frequency analysis (RFA; units of ISQ). Two axes were measured for RFA, designated M and B for the mesial and buccal aspect of the implant.

RAW DATA

Control BLK 1	ITQ	RFA M	RFA B	RTQ
1	9.07	59	56	5.914
2	10.72	57	58	7.936
3	9.498	60	58	5.996
4	12.292	60	58	9.706
5	11.9	59	56	8.722
6	10	58	57	6.39
7	16.34	60	64	10.762
8	8.39	59	59	4.87
9	7.788	58	57	4.274
10	10.978	60	57	6.564
11	14.25	60	58	9.734
12	10.234	61	57	5.954
13	13.59	63	60	8.958
14	14.844	58	58	9.686
15	12.946	60	64	9.476
Avg	11.52	59.47	58.47	7.66

Table 2. Raw data for control block.

RAW DATA

BL2 3.5 df	ITQ	RFA M	RFA B	RTQ
1	9.884	59	56	7.192
2	9.034	58	57	6.074
3	9.818	63	57	7.724
4	9.354	60	57	6.854
5	6.458	58	55	5.278
6	9.668	59	55	7.876
7	11.602	59	57	7.938
8	9.342	61	58	6.798
9	10.746	60	59	7.66
10	10.46	59	55	7.306
11	11.568	63	55	7.444
12	12.494	62	61	9.156
13	12.152	63	59	8.694
14	13.202	64	59	9.848
15	12.446	64	62	8.79
Avg	10.55	60.80	57.47	7.64

Table 3. Raw data for block 2 of the 3.5 mm x 2 mm wide defects.

RAW DATA

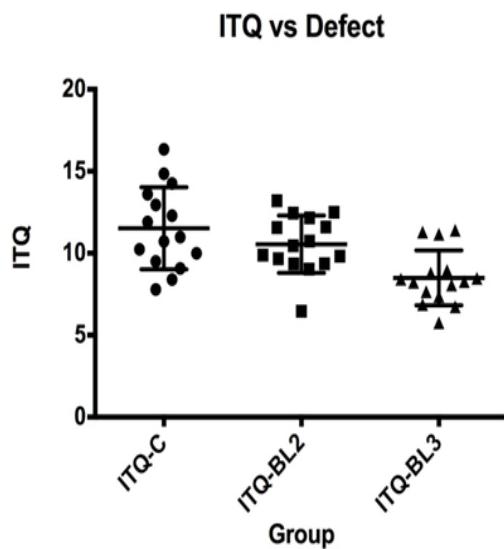
BL3 7.0 df	ITQ	RFA M	RFA B	RTQ
1	8.784	58	56	6.076
2	6.734	59	56	4.224
3	11.402	64	58	7.574
4	11.292	61	58	6.92
5	11.156	60	57	7.014
6	8.068	59	55	6.26
7	8.47	59	57	5.256
8	7.374	59	57	4.976
9	8.276	60	57	5.548
10	8.952	59	56	5.944
11	7.656	59	56	5.734
12	6.862	58	57	4.896
13	5.758	57	55	3.742
14	8.414	61	58	5.984
15	8.23	59	53	6.214
Avg	8.50	59.47	56.40	5.76

Table 4. Raw data for block 3 of the 7.0 mm x 2 mm wide defects.

Descriptive statistics:

The collected data for both the torque (Figure 11a, b) and RFA (Figure 12a, b) measurements showed a relatively close distribution, with narrow standard deviations and a few apparent outliers. An evaluation of the descriptive statistics data (Table 5) showed that each data type (torque and RFA) showed a consistent variance between groups (coefficient of variance ranging from 15.4-21.7% for the torque data and 2.45-4.24% for the RFA data), and the amount of variance was reasonable for experimental data. All torque groups passed two different tests for distribution normality. Also consistent with this, the mean and median values were very close

A



B

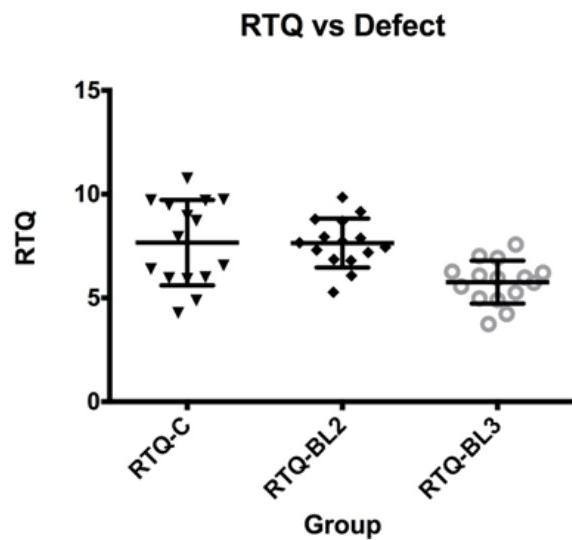


Figure 11: Column scatterplot of Torque data. Bars show mean and standard deviation. **A:** Insertion torque (ITQ); **B:** Removal torque (RTQ).

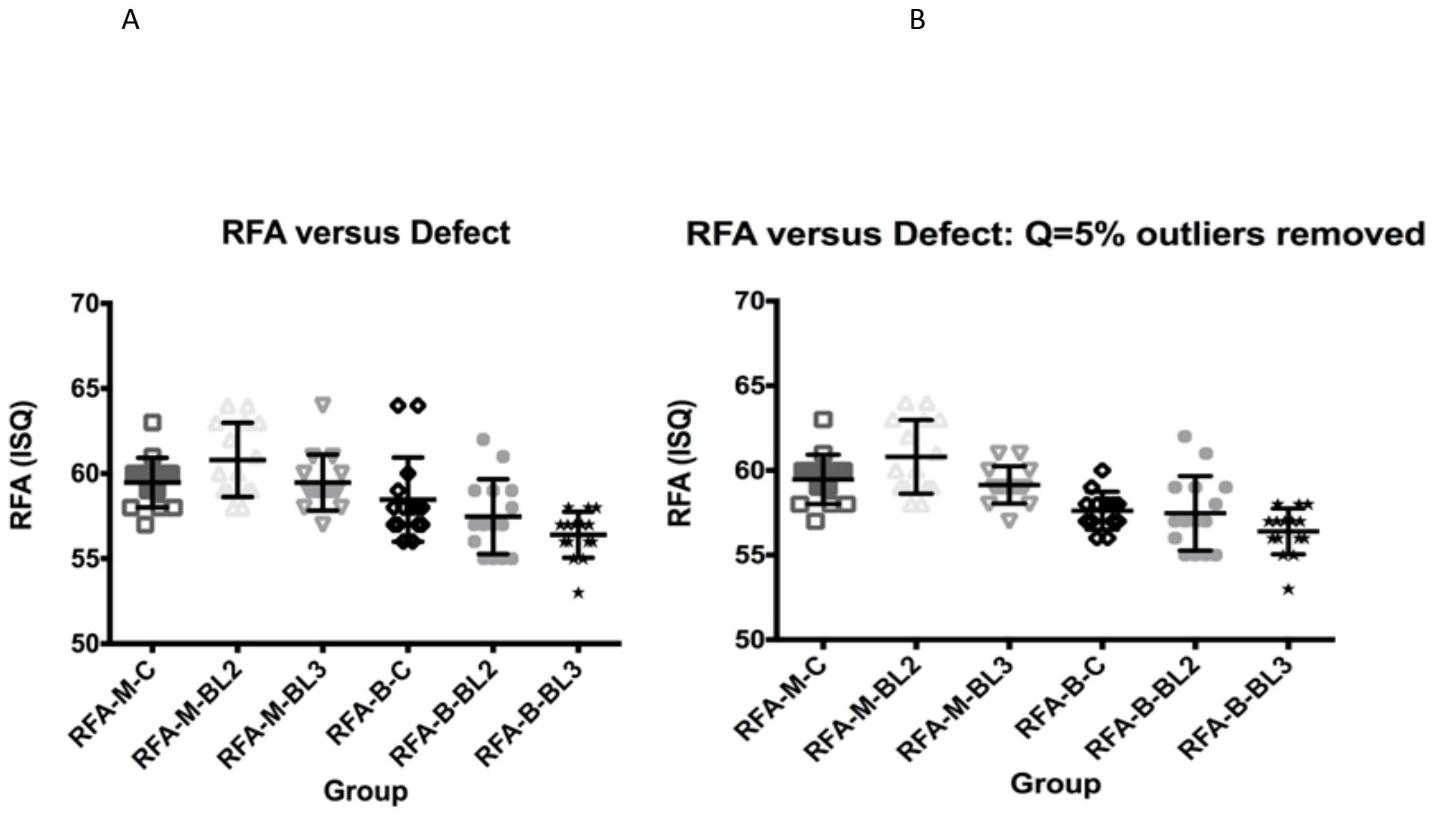


Figure 12: Column scatterplot of RFA data. Bars show mean and standard deviation. **A:** RFA-B and RFA-M all values; **B:** RFA-M. The box shows values removed in B.

As presented in Figure 12a, most RFA groups also show a fairly tight distribution about the mean, although some values appear to be outside of the main group cluster. These outliers are seen in the RFA-M-BL3 and RFA-B-C groups with each tests failing normality for distribution. However, removing these three data points converted both datasets to normal distributions. Because the majority of the data fit normal distributions, and the parametric ANOVA test is pretty strong for moderate divergence from a normal distribution, all data points were kept for this study analysis.

Table 5. Summary of descriptive statistic values:

	ITQ-C	ITQ-BL2	ITQ-BL3	RTQ-C	RTQ-BL2	RTQ-BL3	RFA-M-C	RFA-M-BL2	RFA-M-BL3	RFA-B-C	RFA-B-BL2	RFA-B-BL3
# implants	15	15	15	15	15	15	15	15	15	15	15	15
Med	10.98	10.46	8.276	7.936	7.660	5.944	60.0	60.0	59.0	58.0	57.0	57.0
Mean	11.52	10.55	8.495	7.663	7.642	5.757	59.47	60.80	59.47	58.47	57.47	56.40
stdev	2.500	1.750	1.673	2.056	1.179	1.033	1.457	2.178	1.642	2.475	2.200	1.352
Coeffv%	21.7	16.6	19.7	26.8	15.4	17.9	2.45	3.58	2.76	4.23	3.83	2.40
Norm1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Norm2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes

RESULTS

Inferential statistics

For the four ANOVA tests, a Bonferroni correction was completed for the usual $p=0.05$ is a value of 0.0125. This adjustment to alpha was indicated to reduce the odds of getting a false rejection of the null hypothesis and type I error (Curtin; Schulz 1998).

ITQ

One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect sizes and implant insertion and removal torque (ITQ /RTQ). There were no significant differences seen in the standard deviations. A Browne-Forsythe test ($p=0.16$; Bartlett's test $p=0.25$) and a post-hoc Tukey's multiple comparisons test was completed. The results showed that the 3.5 mm defect had no statistically significant effect on implant stability as measured by insertion torque, but a 7 mm defect showed a significant effect, reducing stability by 26.3% relative to the control and 19.5% relative to the 3.5mm defect. The null hypothesis can be rejected in for the 7mm defect depth group as it relates to ITQ, but not for the control group or the 3.5mm defect depth group.

RTQ

One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect size and removal torque (RTQ) and a p value of 0.0011 was obtained for the ANOVA, indicating significant differences in mean value for RTQ between the groups. A post-hoc Tukey's multiple comparisons was completed and the results

showed that a 3.5 mm defect has no statistically significant effect on implant stability as measured by removal torque, but a 7 mm defect had a significant effect, reducing stability by 24.9% relative to no defect and 24.7% relative to the 3.5 mm defect, very similar to the reduction seen for the insertion torque. The null hypothesis can be rejected pertaining to the 7mm depth defect as it relates to RTQ, but not for the control or the 3.5mm defect group.

RFA

For both the RFA-B and RFA-M a one-way analysis of variance (one-way ANOVA) was used to test each in relationship to defect depths and change in RFA values. Also a post-hoc Tukey's multiple comparisons test was completed and showed that there was no statistically significant effect based on defect depth as compared to the control without defects (Figure 13). In other words there was no reduction in stability as measured by RFA and the null hypothesis cannot be rejected with this test for all groups tested.

Figure 13. Mean RFA values. The bars show standard deviations

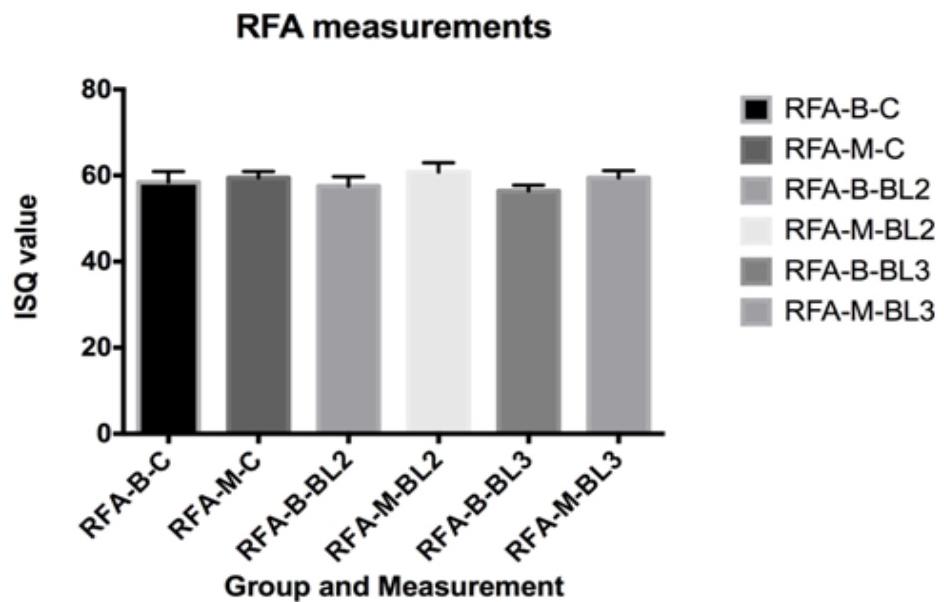




Figure 1 Osstell ISQ, an implant stability meter manufactured by Osstell.

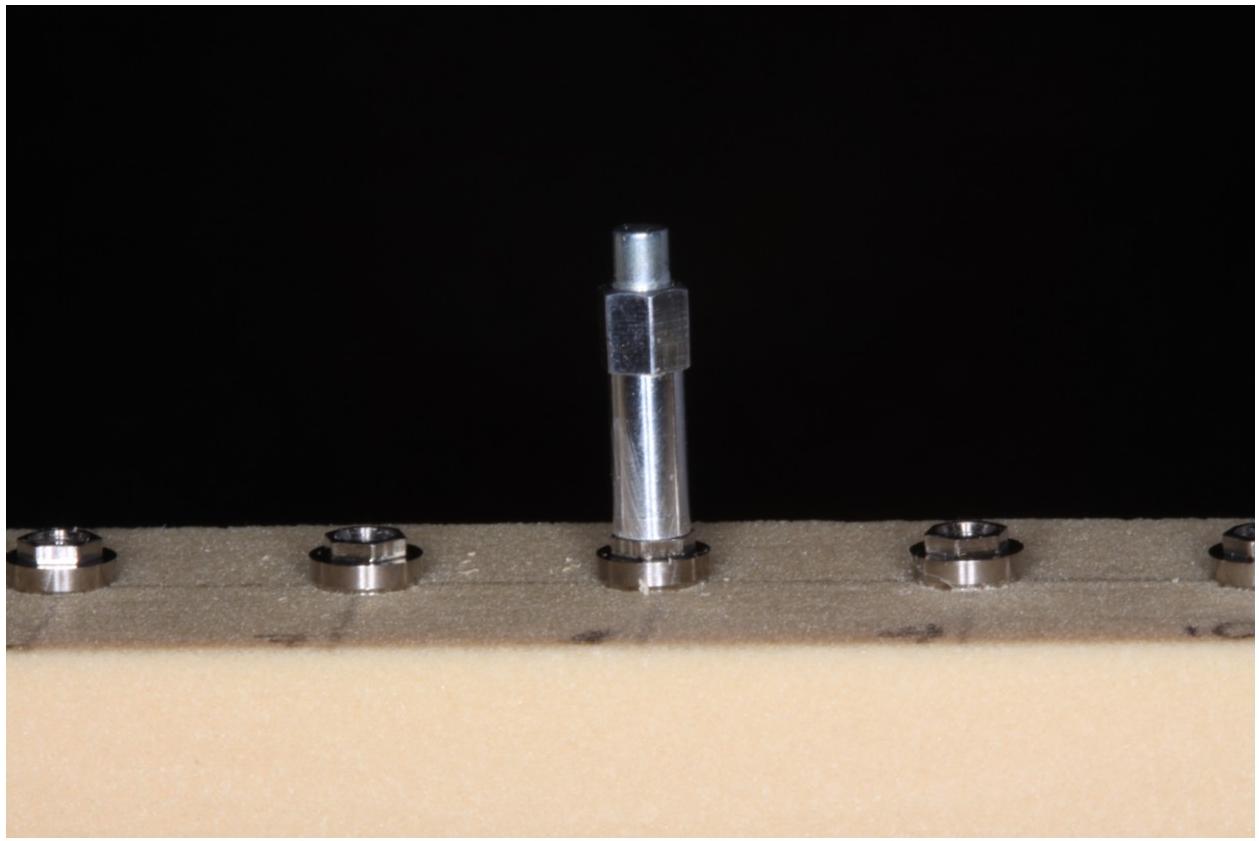


Figure 2. Photo of SmartPeg placed onto a fully seated implant prior to RFA measurements using the Osstell ISQ.

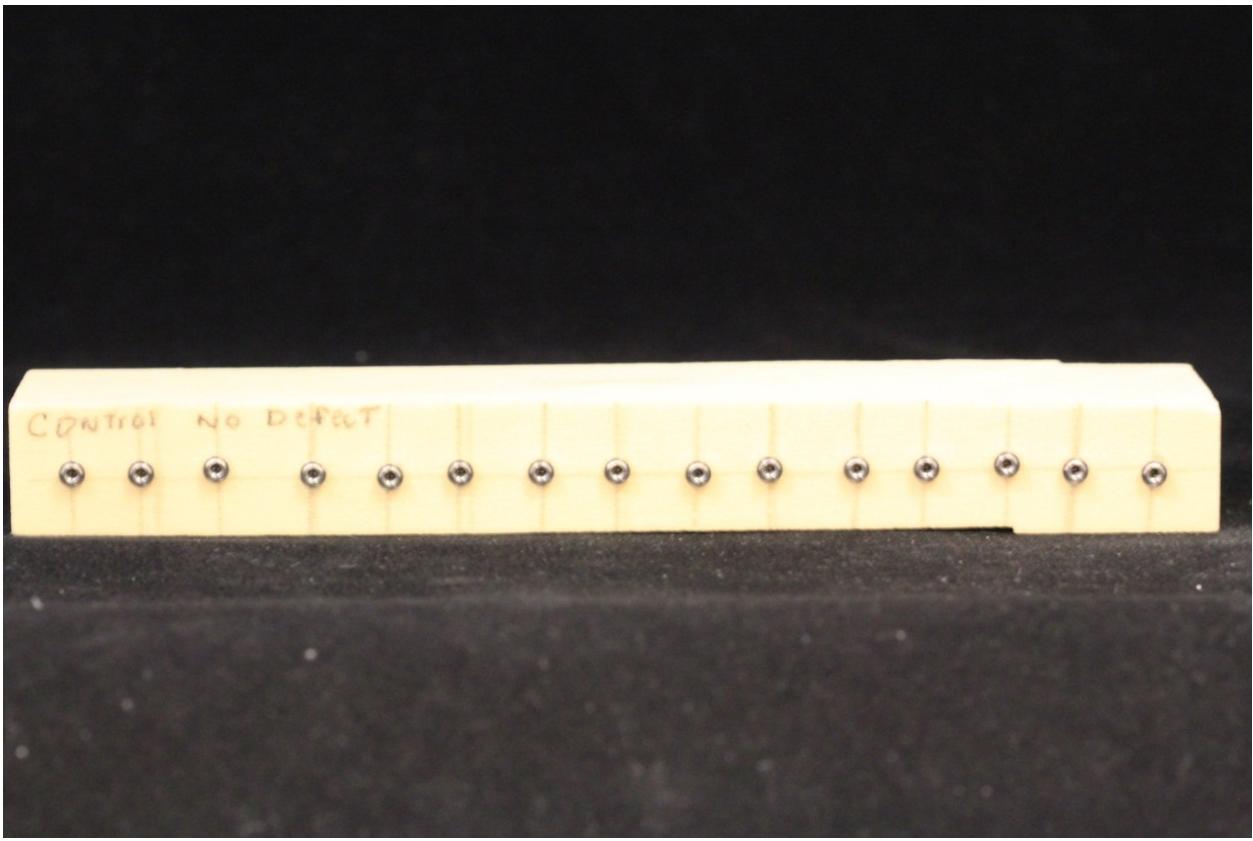


Figure 3. Control block without defects.

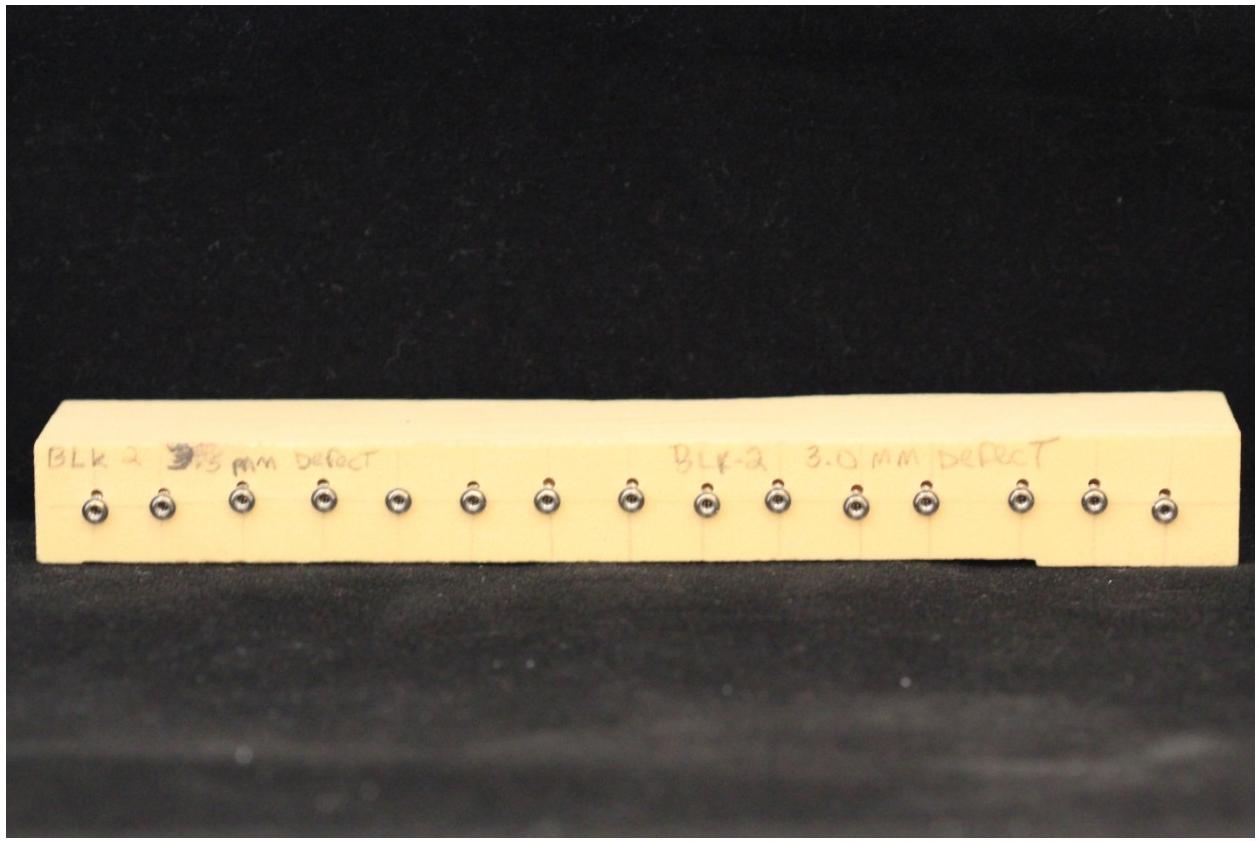


Figure 4. Block 2 with 3.5 mm x 2 mm wide defects.

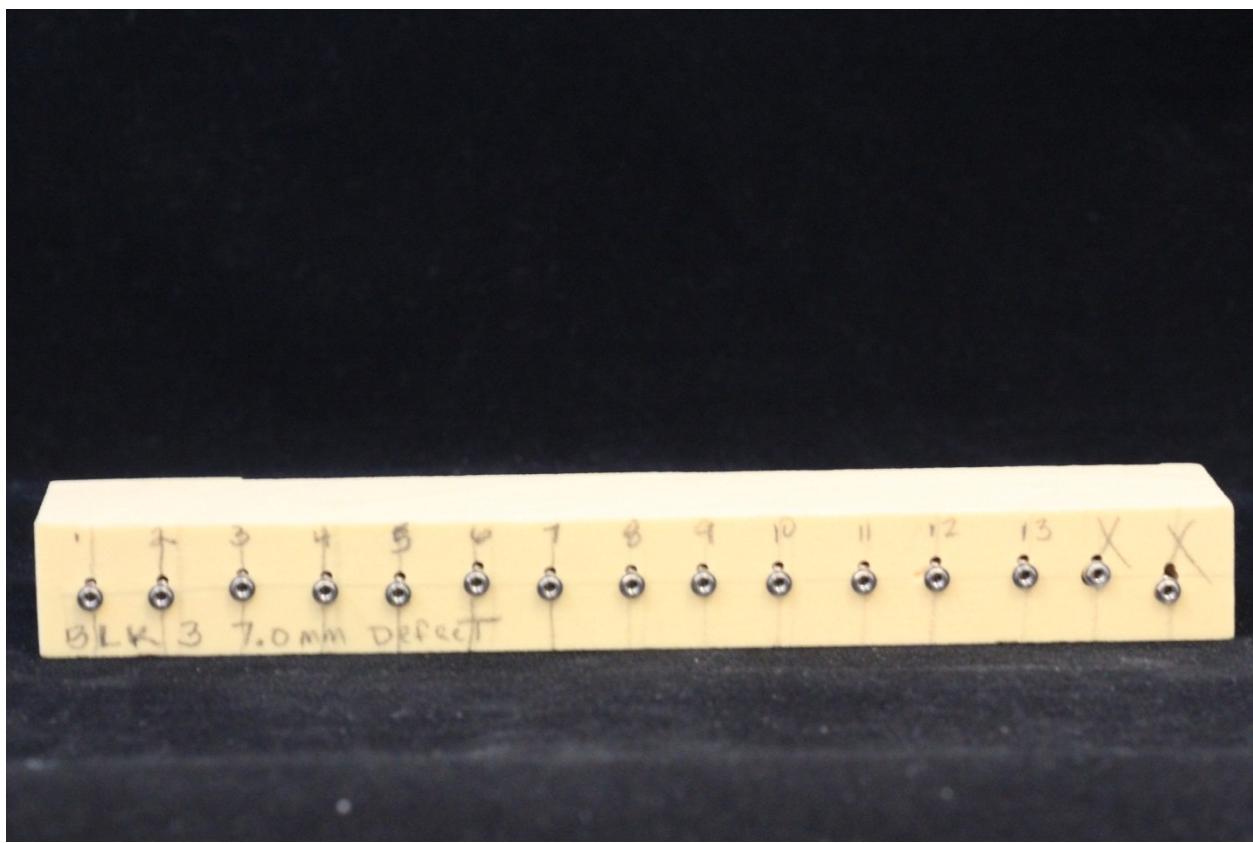


Figure 5. Block 3 with 7.0 mm x2 mm wide defects.

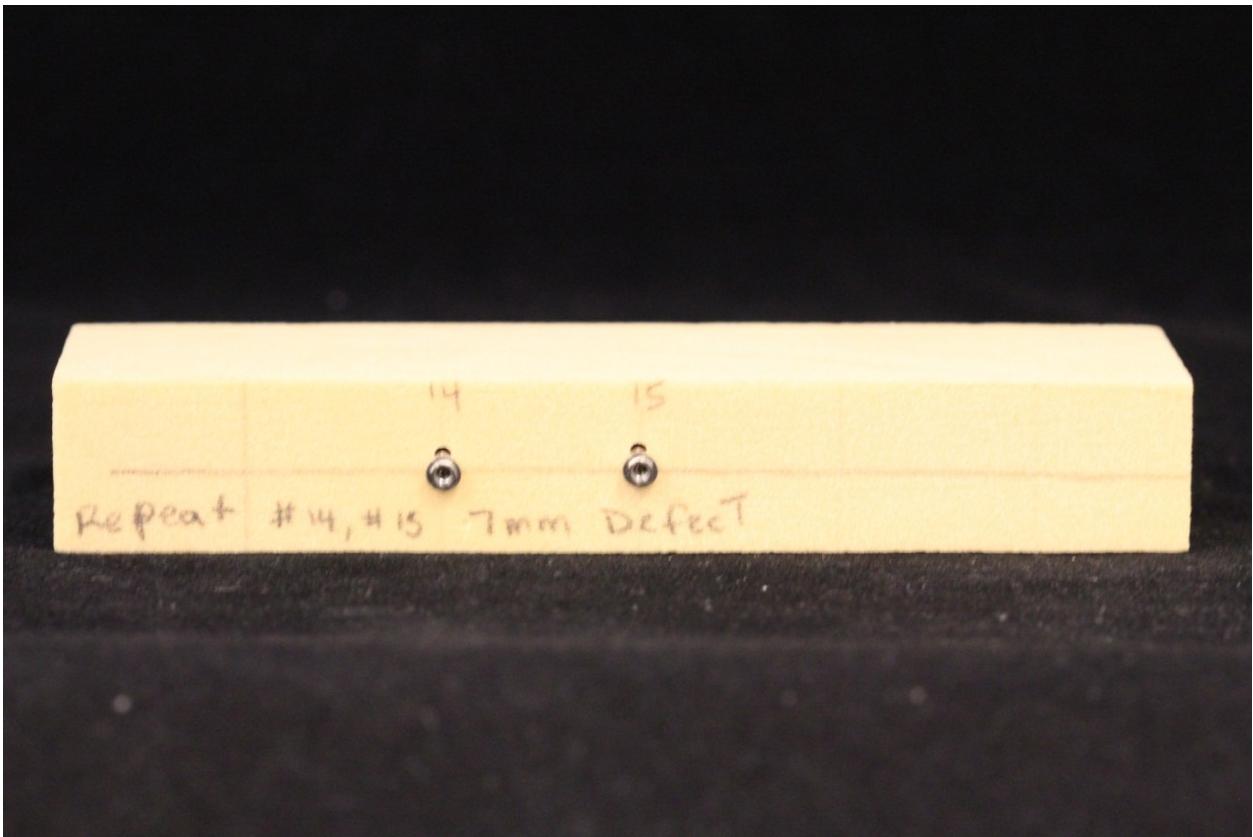


Figure 6. Additional block 3 for implants 14 and 15.



Figure 7. Implants 3.75 x 7 mm used for all blocks in the study.



Figure 8. Af350 precision milling device manufactured by AMANN GIRRBACH.
Used to
ensure osteotomy preparation was always at a fixed angulation.



Figure 9. Photo depicts drills used in this study. From left: 2 mm round drill, 2 mm twisted Drill, 2.4/2.8 x 7-15 mm twisted drill, 3.5 mm twisted drill.



Figure 10. Removal torque measuring equipment (RTQ), developed and manufactured by IM-Teknik Development AB.

DISCUSSION

IMPLANT BEDS

POLYURETHANE FOAM BIOMECHANICAL TEST BLOCKS

Polyurethane foam blocks were chosen for this study as an alternative to real bone due to their success in many other implant studies base on its consistency, ease of use and similarity to human bone. The disadvantages of polyurethane blocks lack the blood cells, platelets, immune/inflammatory response cells and connective tissue involved in bone healing and remodeling. In this study, the biologic healing process associated with implant osseointegration is not evaluated, and only the mechanical aspect of initial implant placement (primary stability) is tested.

Solid rigid polyurethane foam is an alternative test medium to human cancellous bone and can be fabricated to represent different bone densities. Also an epoxy sheet can be applied to represent cortical bone. Numerous implant studies have used polyurethane foam blocks and the material has been recognized as a “standard material for testing” orthopedic devices and instruments (Battula et al., 2006).The polyurethane foam blocks certainly have their advantages in regards to standardizing quality but this can also be a disadvantage as well. In real bone things like blood, heterogeneity, and anisotropy may influence results. Therefore, any results obtained using the polyurethane foam blocks cannot be directly extrapolated to real bone (Thibaut et al., 2009).

The polyurethane foam blocks used in this study were 30 pounds per cubic foot (pcf), solid rigid polyurethane foam blocks representing one uniform density bone

without the epoxy sheet. By using the solid polyurethane foam block as an implant bed for the current study, it represented bone more similar to type III and IV bone, due to the relative absence of a cortical layer. This can be seen when analyzing the mean torque values of a block of 15 implants, with the highest average torque value for all blocks being 19.90 N-cm for insertion torque and 17.50 N-cm for removal torque.

A previous study using various densities of polyurethane blocks without the epoxy sheet showed increased insertion torque (ITQ), and removal torque measurement (RTQ) values with increased cancellous bone density but not resonance frequency analysis (RFA). Only the epoxy coated blocks reflected changes in RFA associated measurements (Bardyn; Gedet, 2009). Important to note is that this result was similar to the result in this study where the RFA did not reflect the changes in bone density due to defect depths. It should be noted that real human bone has a cortical plate that can alter values in RFA and since this was a study using artificial bone without a cortical plate, it can be inferred that RFA values did not represent a true clinical situation. In other words, it was the type of polyurethane block without the epoxy sheet and not the RFA machine causing the lack of correlation to defect depth changes in bone used in this study. Further studies will have to be performed to evaluate this fact.

However, when comparing ITQ and RTQ mean values of 15 implants placed in polyurethane foam blocks, a consistency can be appreciated. For example, if comparing two different defect depths adjacent to implants, it can be said with more confidence that any differences in stability measurements is related to the defects and not the polyurethane foam blocks which have a consistent density throughout.

Implant placement depth

All implants in this study were allowed to be inserted into the implant bed by the RTQ machine and manually stopped by the researcher. The rotation speed used in this study allowed for time to stop the implant as soon as the threads disappeared into the osteotomies. It was difficult to stop all the implants at the same depth.

Efforts in stopping all the implants at the same final insertion depths were enhanced by using headlamps and dental loupes. Given this study design, slight variations in implant final positions were possible and may have been affected final insertion torque values or allowed the implant to continue to the actual depth of the osteotomy preparations. To establish a more consistent depth of implant placement, an indelible mark on the implant collar could have been placed which would have allowed for a visual stopping point. Also, having an additional person at the computer to push the stop button would have been beneficial. However, the method chosen was very similar to how the process is completed in-vitro and it was thought that the differences would be minimal as final depth would differ by only fractions of millimeters.

RTQ/ITQ

When evaluating the effect of bony defects had on ITQ and RTQ, the 3.5mm defect had no statistically significant effect on insertion torque or removal torque. Although, the 7.0mm defect did have a significant effect on implant stability relative to the control without defects. It is important to mention in this in vitro study, that block 2 had 3.5 mm of synthetic polyurethane bone circumferentially below the 3.5mm defect and the 7.0mm defect did not. The 7.0mm defect was placed at total length of the implant. So in other

words, the defect extending to the tip of the implant in the 7.0mm defect was not contacting the bone circumferentially. This was what this study was evaluating and looking to establish based on defect depths. Clinically, the implant-bone interface can be classified as Type I, II, III and ideally one would prefer to see an implant with freshly prepared bone along its complete periphery (Type 1) when the root is smaller than the implant. Type II represents the bony defect present at the coronal aspect, while the apical portion of the implant is secured in freshly prepared bone. This represented block 2 of the 3.5mm defect group. Type III represents the bony defects prepared in block 3 with a 7.0mm defect group where the space is present along the lateral border of the implant.

Based on previous literature, in order to gain primary implant stability in immediate implant placement, at least 3.0mm of circumferential bone implant contact must exist or 3-5mm past the extraction socket into the bone. (Touati,B; Guez,G 2002). This 3mm BIC recommendation was not present in the (block 3) 7.0mm implant group that presented a reduction in stability reflected by both ITQ and RTQ. The 3.5mm defects were not deep enough or wide enough to significantly reduce primary stability based on the similar values seen when compared to the control group (no defects). Clinically, and based on these results, a defect extending full length of an implant may not have enough primary stability for the placement of a healing abutment or immediate loading. A clinician must establish the extent of a defect/space adjacent to an implant from insertion/ final torque measurements, radiographs and clinical judgment.

Further studies could evaluate the effect of a defect width greater than 2mm at the same length and evaluate the insertion torque and removal torque. From this present

study, the depth of a defect did alter its primary stability and bone implant contact in the 7.0mm x 2mm wide defect group. Clinical evaluation of good bone to implant contact is established by using a hand held implant torque wrench. Torqueing the implant to a final 35N-cm is an indication of adequate primary implant stability, but some authors (Touati, guez, 2002) say a final torque of 45 – 60 N-cm is the recommended primary stability. This hand held torque wrench may have provided some valuable information in this study when comparing final torques of the three test blocks. Would the different defect depths show different torque values using the hand held torque wrench? Further testing would have to be done to evaluate this relationship.

RFA

In this study the slightly lower RFA values reflect the non-corticated bone with highest numbers of 64 ISQ. The implants were measured from the mesial (RFA-M) and buccal (RFA-B) aspects of the implants and the results showed that both are indistinguishable from the control group without defects, but in the presence of a 3.5 mm or 7.0 mm defect, there is a small but statistically significant decrease in the RFA-B relative to the RFA-M. But, for an individual implant, the size of this decrease in value is comparable to the variance seen in the control group. The means of the RFA-M and RFA-B did not show a relationship to bone defect and in turn primary implant stability. The slight reduction in value of the RFA-B could have occurred because the fabricated defect was located opposite and in the line of “fire” as the RFA hand held wand. This is in the direction of the actual defect as opposed to the RFA-M aspect of the implant. In the defect groups the RFA measurements did not reflect the reduction in stability as was seen in the ITQ and RTQ measurements.

Since RFA did not show significantly reduced values and were consistent with all samples, it can be inferred that they all had primary stability. It is possible that the defects were not wide enough to alter the stiffness that can be detected by the Osstell ISQ/RFA machine or that RFA is not sensitive to non-corticated coated polyurethane blocks as was previously mentioned.

Because negative moderate correlations were noted between RFA vs. ITQ/RTQ, a true relationship between these variable cannot be proven. An absence of correlation between RFA and torque has been reported in literature before (Akkocaoglu and Tekdemir, 2007; Nkenkeet al., 2003; O'Sullivan and Meredith, 2000). Another study showed no correlation between RFA and RTQ and suspected it could be due to the RFA being influenced by both the cortical and trabecular layers, where removal torque is more influenced by the trabecular layer (Thibaut et al., 2009). Since only trabecular bone was used in this study, the lack of correlation in this study may be related to absence of a cortical plate. More research would be necessary to study this potential correlation.

CONCLUSIONS

Implant insertion/removal torque and bone defect depth show a non-linear relationship, with only the largest defect tested (7mm) showing a moderate decrease in insertion torque. Neither of the means for RFA-B or RFA-M showed any significant relationship to bone defect depth. Since there was no significant difference in RFA-M and RFA-B in relationship to bone defects, is there primary implant stability? Based on RFA alone, there is primary implant stability in all the implants placed. In contrast, the ITQ/RTQ reflected implant stability in the 3.5 millimeter defect but not the 7.0 millimeter defect. In the 7.0mm defect group primary stability was reduced by 24.9% in RTQ values and 26.3% in ITQ values comparing their effects on primary implant stability with the control group and 3.5mm group. Using RFA as a measure of primary implant stability is a good adjunct determining primary implant stability but should not be the only tool used to determine if implants will osseointegrate and become successful in this aspect. Final torque, bone quality and type, patient physical status, medications and radiographs should all be taken into account when treatment planning where when and how to place the implant. Based on this in vitro study, the RFA indicated that the defect groups had primary implant stability but the ISQ values did not mirror the ITQ and RTQ measurements that showed reduced stability. Further studies need to be conducted to investigate these parameters to establish confidence in RFA clinically verses an in vitro study on reduced implant bone contact.

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Appendix: Statistical Analysis

Title: IN-VITRO MEASUREMENT OF INSERTION TORQUE, REMOVAL TORQUE AND RESONANCE FREQUENCY ANALYSIS OF IMPLANTS PLACED INTO SIMULATED BONY DEFECTS.

Investigator: LTC George A. Quiroa, Fort Bragg, NC

Prepared by: Douglas P. Dickinson, PhD

Summary (adapted from proposal): This is an in vitro, non-human study placing dental implants into synthetic bones. The primary objective of this study is to investigate the potential effects of reduced bone support around dental implants as determined by primary implant stability, as judged by measurement of the implants insertion torque (ITQ), resonance frequency analysis (RFA), and removal torque (RTQ). RFA was determined along two axes, designated M and B. Three groups of 15 implants were placed in artificial bone. 15 implants were placed with no bone defects adjacent to the implants to serve as a control group. 15 implants were placed with 2mm wide by 3.5mm deep bone defects adjacent to the implants. Another 15 implants were placed with 2mm wide by 7mm deep bone defects.

A better understanding of factors pertaining to primary implant stability would lead to better preoperative planning and more predictable implant success.

Samples: Implants were Nobel Biocare 3.75 mm X 7mm implants 45 implants were divided into three groups of 15. One group (control) was placed at full length (7 mm) in synthetic bone with no defect. A second group (BL2) was placed in bone with a 2 mm wide x 3.5 mm deep adjacent defect. The third (BL3) was placed in bone with a 2 mm wide x 7 mm deep adjacent defect.

Independent variable(s): There is one categorical ordinal independent variable, defect depth. This factor has three levels in increasing order of defect severity; none, 3.5 mm and 7 mm.

Dependent variables: There were three types of measurements made: insertion torque (ITQ; units of Ncm); removal torque (RTQ; units of Ncm); and resonance frequency analysis (RFA; units of ISQ). Two axes were measured for RFA, designated M and B. This gave four sets of data per factor level. These variables are continuous.

Research question (paraphrased): (1) what is the relationship between insertion torque and bone defect depth? (2) What is the relationship between removal torque and bone defect depth? (3) What is the relationship between RFA and bone defect depth?

It was hypothesized that implant stability, as measured by these parameters, would decline with defect depth. No predictions were made regarding correlations.

Assumptions about sampling: The individual implants ("subjects") in each group are assumed to be random samples from the group population.

Graphpad Prism 6.0 software was used for statistical analysis.

1) Descriptive statistics:

The data for both the torque (Figure 1a,b) and RFA (Figure 2a,b) measurements showed a relatively tight distribution, with narrow standard deviations and few apparent outliers. Inspection of the descriptive statistics data (Table 1) showed that each data type (torque and RFA) showed a consistent variance between groups (coefficient of variance ranging from 15.4-21.7% for the torque data and 2.45-4.24% for the RFA data), and the amount of variance was not unreasonable for experimental data. All torque groups passed two different tests for distribution normality. Consistent with this, the mean and median values were very close.

Figure 1: Column scatterplot of Torque data. Bars show mean and standard deviation. **A:** Insertion torque (ITQ); **B:** Removal torque (RTQ).

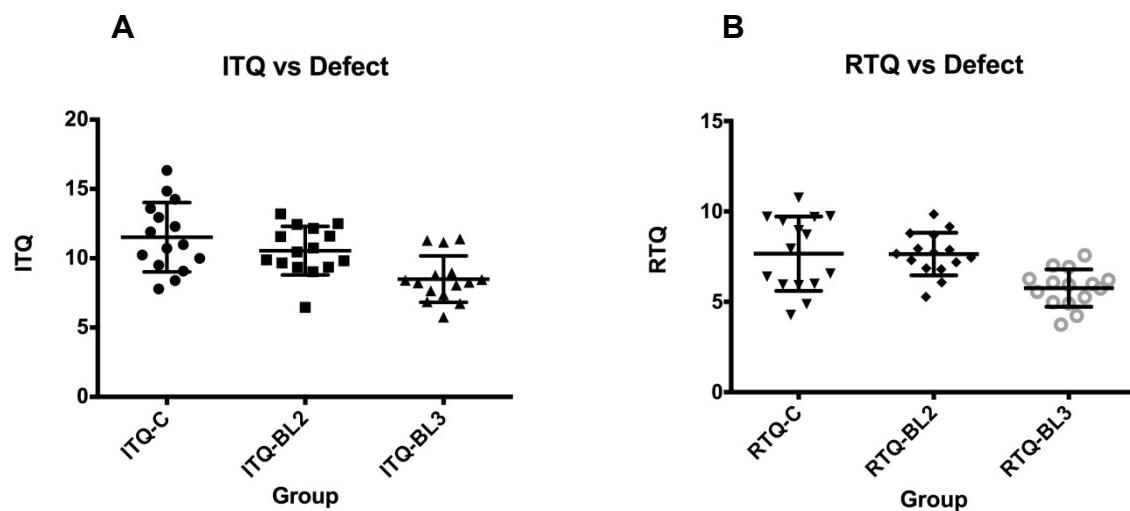
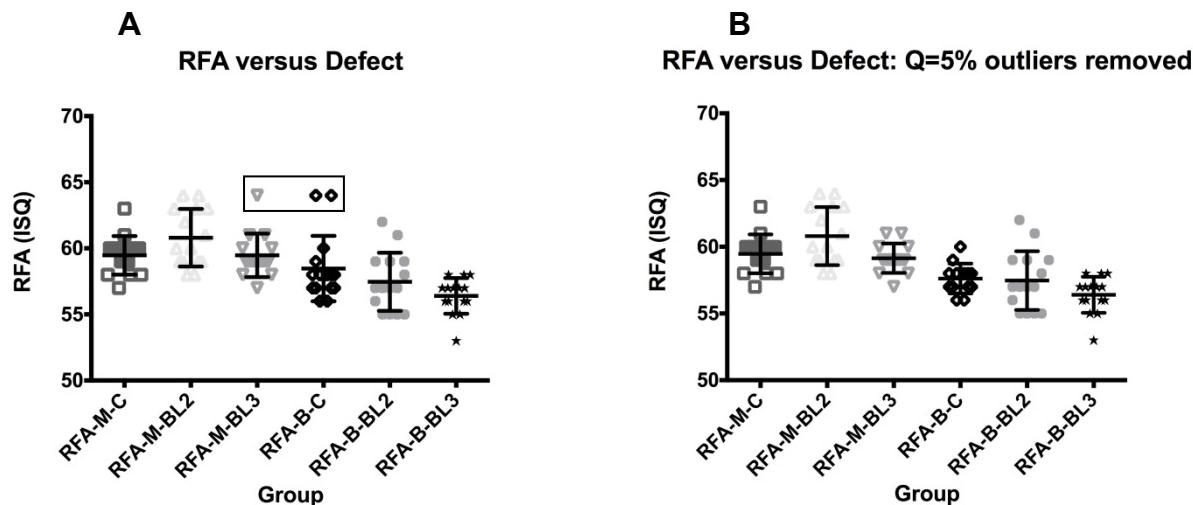


Figure 2: Column scatterplot of RFA data. Bars show mean and standard deviation. **A:** RFA-B and RFA-M all values; **B:** RFA-M. The box highlights values removed in B.



As shown in Figure 2a, most RFA groups also show a fairly tight distribution about the mean, although some values appear to be some distance outside of the main cluster. The RFA-M-BL3 and RFA-B-C groups each failed both tests for distribution normality, and each had a kurtosis >2; the skewness was moderately high. As shown in Figure 2b, a ROUT test for outliers under relaxed criteria (Q=5%) only identified 3 candidate outliers (one in RFA-M-BL3, two in RFA-B-C, consistent with visual inspection), but these were not detected under more stringent criteria (Q=1%). However, removing these three data points converted both datasets to normal distributions. Since the majority of the data fit normal distributions, and parametric ANOVA is relatively robust towards moderate divergence from a normal distribution, all data points were retained for analysis.

Summary descriptive statistic values.

	ITQ-C	ITQ-BL2	ITQ-BL3	RTQ-C	RTQ-BL2	RTQ-BL3	RFA-M-C	RFA-M-BL2	RFA-M-BL3	RFA-B-C	RFA-B-BL2	RFA-B-BL3
n	15	15	15	15	15	15	15	15	15	15	15	15
Med	10.98	10.46	8.276	7.936	7.660	5.944	60.0	60.0	59.0	58.0	57.0	57.0
Mean	11.52	10.55	8.495	7.663	7.642	5.757	59.47	60.80	59.47	58.47	57.47	56.40
stdev	2.500	1.750	1.673	2.056	1.179	1.033	1.457	2.178	1.642	2.475	2.200	1.352
Coeffv%	21.7	16.6	19.7	26.8	15.4	17.9	2.45	3.58	2.76	4.23	3.83	2.40
Norm1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Norm2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Skew	0.362	-0.577	0.580	-0.135	-0.069	-0.241	0.635	0.247	1.465	1.629	0.656	-1.056
Kurt	-0.701	0.644	-0.152	-1.420	0.217	-0.069	1.418	-1.582	3.495	2.013	-0.259	1.546

Norm1: D'Agostino& Pearson omnibus normality test; p=0.05. Norm2: Shapiro-Wilk normality test; p=0.05

2) Inferential statistics

For four ANOVA tests, a Bonferroni correction for the usual $p=0.05$ is a value of 0.0125.

a) Evaluation of Torque data

(i) ITQ (Research Question#1): One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect size and implant torque (insertion and removal). No significant differences in standard deviations were seen (Browne-Forsythe test $p=0.16$; Bartlett's test $p=0.25$). Therefore, the assumptions of the test are valid. A p value of 0.0006 was obtained, indicating significant differences in mean value for ITQ between the groups. A post-hoc Tukey's multiple comparisons test showed that there was no significant difference between the ITQ means in the control and the BL2 3.5 mm defect groups (adjusted $p=0.39$). However, the BL3 7 mm defect group ITQ mean was significantly lower than the ITQ mean in the control (adjusted $p=0.0005$; mean difference 3.027 Ncm; 26.3% lower than control) and the BL-2 3.5 mm (adjusted $p=0.021$; mean difference 2.053 Ncm; 19.5% lower than BL-2) groups.

These results show that a 3.5 mm defect has no statistically significant effect on implant stability as measured by insertion torque, but a 7 mm defect has a significant effect, reducing stability by 26.3% relative to no defect.

(ii) RTQ (Research Question #2): One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect size and removal torque (insertion and removal). A significant difference in standard deviations was seen (Browne-Forsythe test $p=0.0013$; Bartlett's test $p=0.021$). Therefore, this assumption of the test was not valid. Inspection of the standard deviations revealed a near 2-fold difference between the RTQ-C and RTQ-BL3 datasets, with the variance paralleling the means of the groups. This difference is modest, and these tests are known to be sensitive. Since the ANOVA is relatively robust to violations of equality with equal group sizes, the results were considered acceptable, with a caution regarding over-interpreting p values not much lower than 0.05.

A p value of 0.0011 was obtained for the ANOVA, indicating significant differences in mean value for ITQ between the groups. A post-hoc Tukey's multiple comparisons test showed that there was no significant difference between the ITQ means in the control and the BL2 3.5 mm defect groups (adjusted $p\sim 1.0$). However, the BL3 7 mm defect group ITQ mean was significantly lower than the ITQ mean in the control (adjusted $p=0.0032$; mean difference 1.905 Ncm; 24.9% lower than control) and the BL-2 3.5 mm (adjusted $p=0.0035$; mean difference 1.885 Ncm; 24.7% lower than BL-2) groups.

These results show that a 3.5 mm defect has no statistically significant effect on implant stability as measured by removal torque, but a 7 mm defect has a significant effect, reducing stability by 24.9% relative to no defect, very similar to the reduction seen for insertion torque.

b) Evaluation of RFA data (Research Question #3)

(i) RFA-B. One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect size and RFA-B values. No significant differences in standard deviations were seen (Browne-Forsythe test $p=0.46$; Bartlett's test $p=0.088$). Therefore, the assumptions of the test are valid.

A p value of 0.0315 was obtained for the ANOVA. This was below 0.05, but it was not below 0.0125. Although the Bonferroni correction is considered conservative, this test result is not statistically significant. A post-hoc Tukey's multiple comparisons test showed that there was no significant difference between the RFA-B means in the control and the BL2 3.5 mm defect groups (adjusted $p =0.39$), and no significant difference between the means in the BL2 3.5 mm and the BL3 7 mm defect groups (adjusted $p =0.34$). However, the BL3 7 mm defect group RFA-B mean was significantly lower than the mean in the control (adjusted $p=0.0238$; mean difference 2.066 ISQ). Since the RFA-B control group failed both tests for normality with 2 out of 16 candidate outliers (ROUT $Q=5\%$), these outliers were removed and a second ANOVA conducted (without further Bonferroni correction). The data now passed the Browne-Forsythe test, but failed Bartlett's test. However, the ANOVA no longer gave a significant value ($p =0.11$).

These results show that mean RFA-B values have no significant relationship to defect size.

(ii) RFA-M. One-way analysis of variance (one-way ANOVA) was used to test the relationship between defect size and RFA-M values. No significant differences in standard deviations were seen (Browne-Forsythe test $p=0.12$; Bartlett's test $p=0.30$). Therefore, the assumptions of the test are valid. A p value of 0.073 was obtained, indicating no significant differences in mean value for RFA-M between the groups.

These results show that mean RFA-M values have no significant relationship to defect size.

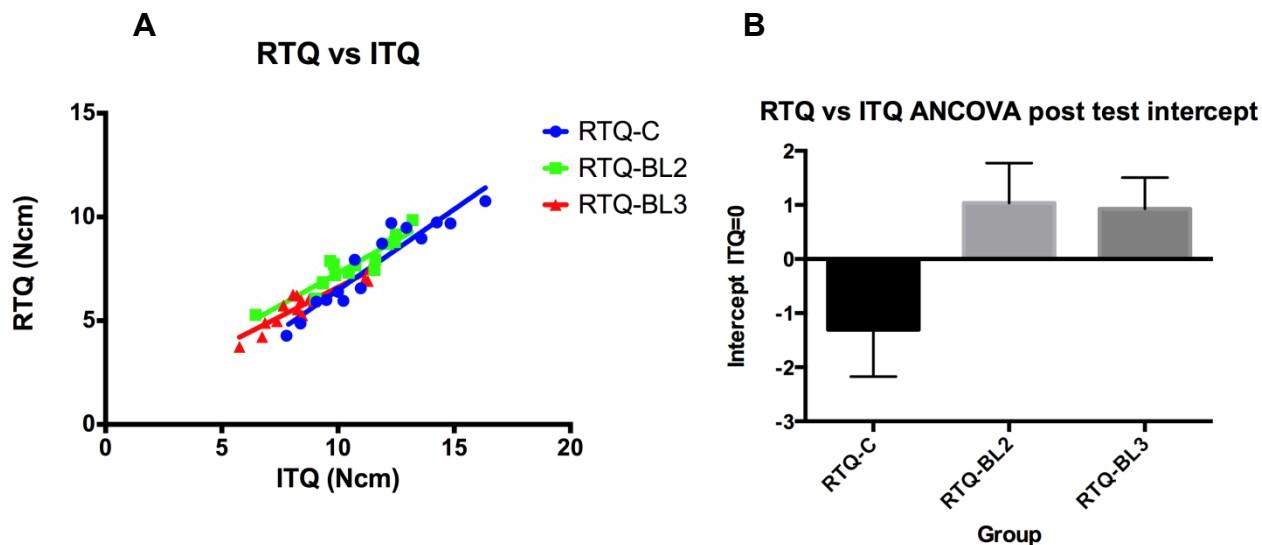
c) Analysis of ITQ and RTQ relationship

To investigate the relationship between ITQ and RTQ values and the effect of defect size on any relationship, an equivalent of ANCOVA was performed by conducting a linear regression analysis of RTQ versus ITQ for each defect group, followed by an ANOVA of the slopes to test the null hypotheses that the slopes do not differ, and if appropriate, that the intercepts do not differ.

(i) RTQ versus ITQ Linear regression. The x-y scatterplots of RTQ versus the covariate ITQ for each defect group are shown in Figure 3. There is a distinct linear relationship pattern between RTQ and ITQ in each defect group, with few obvious outliers. There is a trend for the points representing data pairs to lie closer to the origin with increasing defect size, although the control group values are spread over a larger

range. Linear regression for RTQ versus ITQ for each defect group gave Goodness of Fit R^2 values of 0.8958 (control), 0.8638 (BL2 3.5 mm), and 0.8479 (BL3 7 mm), indicating a strong positive correlation between RTQ and ITQ. All three slopes were highly significantly non-zero ($p<0.0001$).

Figure 3. Analysis of the relationship between RTQ and ITQ. **A:** xy scatter plots of RTQ versus ITQ for each implant group are shown. Lines show linear regression fits to the group data. **B:** RTQ intercept values determined from ANCOVA.



(ii) **RTQ versus ITQ ANCOVA.** The slopes of each regression line did not differ significantly ($p=0.094$), but the axis intercepts did ($p=0.0074$). With ITQ set to zero, the RTQ intercepts were: RTQ-C, -1.307 ± 0.867 ; RTQ-BL2, 1.034 ± 0.737 ; and RTQ-BL3, 0.9266 ± 0.577 Ncm. An ANOVA test of these values with a Tukey's post test showed a highly significant ($p<0.0001$) difference between the control intercept and the intercepts for the other two defect groups; the defect groups did not show a significant difference (mean value 0.9803 ± 1.1840)(Figure 3B). Therefore, the control group RTQ intercept (at ITQ=0) was 2.287 ± 1.468 Ncm lower than the defect groups.

These results show that there is a linear relationship between RTQ and ITQ in each group with the same slope regardless of defect. The relationship between RTQ and ITQ was statistically the same for both the 3.5 and 7 mm defect groups, but the line for the control group was shifted to the right. This is equivalent to the control group insertion torque for an individual implant being 2.287 ± 1.468 Ncm greater than the removal torque for an implant at a defect site with the same value insertion torque. This suggests that for a given RTQ, a higher torque is required to insert an implant at a site without a defect than with.

c) Analysis of RFA-B and RFA-M relationship.

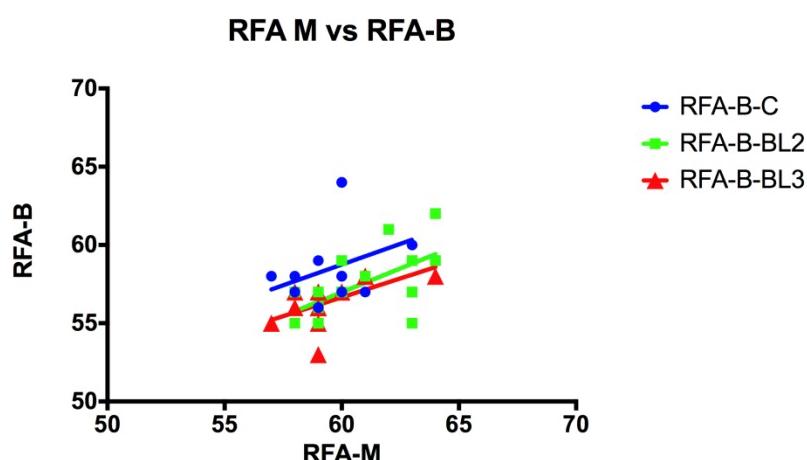
To investigate the relationship between RFA-B and RFA-M values and the effect of defect size on any relationship, an equivalent of ANCOVA was performed by conducting a linear regression analysis of RFA-B versus RFA-M for each defect group, followed by an ANOVA of the slopes to test the null hypotheses that the slopes do not differ, and if appropriate, that the intercepts do not differ.

(i) RFA-B versus RFA-M Linear regression. The x-y scatterplots of RFA-B versus the covariate RFA-B for each defect group are shown in Figure 4. There is an appearance of linear relationship pattern between RFA-B and RFA-M in each defect group, but there is considerable scatter, and no obvious trend between the groups. Linear regression for RFA-B versus RFA-M for each defect group gave Goodness of Fit R^2 values of 0.0971, (control), 0.0.3629, (BL2 3.5 mm), and 0.3429, (BL3 7 mm). The lack of any significant correlation between RFA-B and RFA-M in the control group was consistent with the lack of any significant difference from zero for the slope of the regression line ($p=0.26$). That is, given the narrow standard deviation for the control group, the RFA-B and RFA-M values likely differ only by random variation. For the defect groups, there was a moderate correlation between RFA-B and RFA-M, and a significant difference from zero for the slope (BL2 3.5 mm, $p=0.016$, BL3 7 mm $p=0.022$).

(ii) RFA-B versus RFA-M ANCOVA. Since there was no correlative relationship between RFA-B and RFA-M in the control group, these data were omitted from the next step of the analysis. The slopes of the defect group regression lines did not differ significantly ($p=0.69$), and the axis intercepts did differ significantly ($p=0.59$). Therefore, RFA-B and RFA-M had the same relationship in the BL2 3.5 mm and BL3 7 mm defect groups.

These results show that there is the same linear relationship between RFA-B and RFA-M in each defect group regardless of defect size, but in the control group they show no relationship.

Figure 4. Analysis of the relationship between RFA-B and RFA-M. X-Y scatter plots of RFA-B versus RFA-M for each implant group are shown. Lines show linear regression fits to the group data.

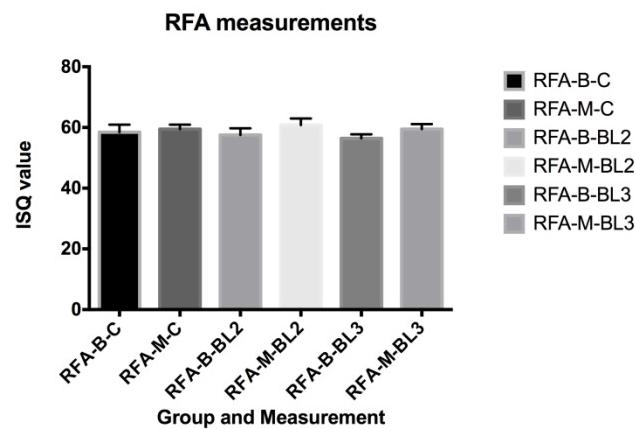


(iii) RFA-B versus RFA-M repeated measures t-test. The null hypothesis for this test is that within each group, RFA-B and RFA-M show the same mean value. For each

implant group, a difference between the values for RFA-B and RFA-M (Figure 5) was examined using a repeated measures t-test. For three group tests, a Bonferroni correction to alpha =0.0167 was applied. In the control group, there was no significant difference ($p=0.14$) between the mean RFA-B value (58.47) and the mean RFA-M value (59.47). In the BL2 3.5 mm defect group, there was a highly significant ($p<0.0001$) - 3.33 unit difference between RFA-B and RFA-M. In the BL3 7 mm defect group, there was a highly significant ($p<0.0001$) -3.07 unit difference between RFA-B and RFA-M. That is, RFA-B was 5.3-5.5% lower than RFA-M when a defect was present.

These results show that RFA-B and RFA-M are statistically indistinguishable in the absence of a defect, but the presence of a 3.5 or 7 mm defect produces a small, but statistically significant decrease in RFA-B relative to RFA-M. However, for an individual implant, the size of this decrease is comparable to the variance seen in the control group.

Figure 5. Mean RFA values. The bars show standard deviations.



d) Analysis of RFA and RTQ relationship.

To investigate the relationship between RFA and RTQ values and the effect of defect size on any relationship, an equivalent of ANCOVA was performed by conducting a linear regression analysis of RFA-B and RFA-M *versus* RTQ for each defect group, followed by an ANOVA of the slopes to test the null hypotheses that the slopes do not differ, and if appropriate, that the intercepts do not differ.

(i) RFA-B *versus* RTQ Linear regression. The x-y scatterplots of RFA-B versus the covariate RTQ for each defect group are shown in Figure 6A. There is an appearance of linear relationship pattern between RFA-B and RTQ for the control and BL2 3.5 mm defect groups, but there is considerable scatter. There is an indication of a trend towards the origin with increasing defect size. Linear regression for RFA-B *versus* RTQ for each defect group gave Goodness of Fit R^2 values of 0.2864, (control), 0.4110, (BL2 3.5 mm), and 0.0779, (BL3 7 mm). There was a significant difference from zero for the slope in the control ($p=0.040$) and BL2 3.5 mm group ($p=0.010$), but not in the BL3 7 mm group ($p=0.31$).

(ii) RFA-B *versus* RTQ ANCOVA. Since there was no correlative relationship between RFA-B and RTQ in the BL3 7 mm group, these data were omitted from the next step of

the analysis. The slopes of the defect group regression lines did not differ significantly ($p=0.29$), and the axis intercepts did differ significantly ($p=0.18$). Therefore, RFA-B and RTQ had the same relationship in the control and BL2 3.5 mm and defect groups.

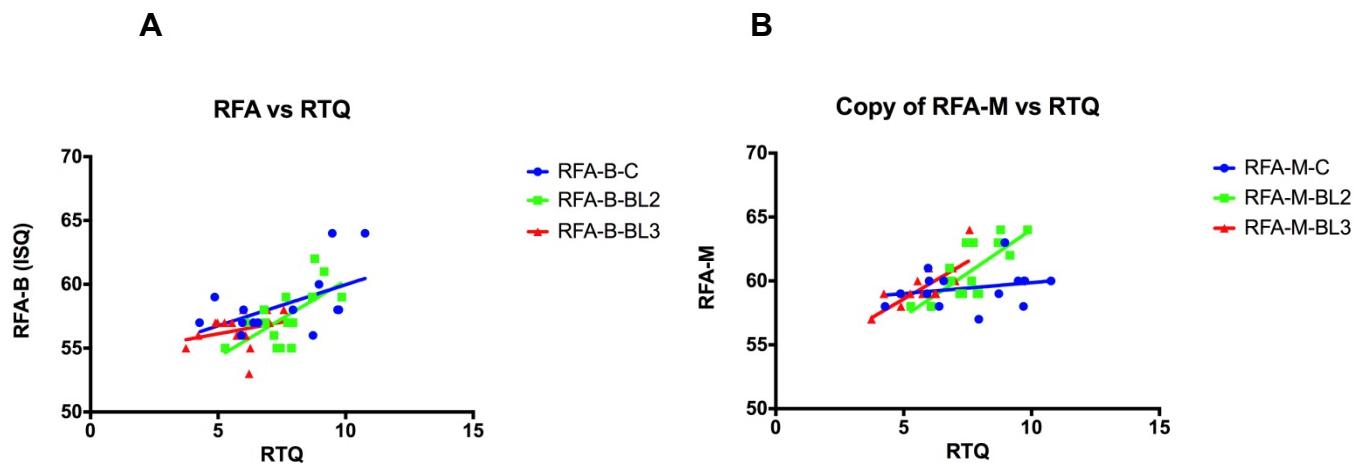
These results show that there is the same linear relationship between RFA-B and RTQ in the control and BL2 3.5 mm defect group, but in the BL3 7 mm group they show no relationship.

(iii) RFA-M versus RTQ Linear regression. The x-y scatterplots of RFA-M versus the covariate RTQ for each defect group are shown in Figure 6B. There is an appearance of linear relationship pattern between RFA-M and RTQ for the BL2 3.5 mm and BL3 7 mm defect groups, but not for the control. Linear regression for RFA-M versus RTQ for each defect group gave Goodness of Fit R^2 values of 0.0582, (control), 0.5443, (BL2 3.5 mm), and 0.5421, (BL3 7 mm). There was no significant difference from zero for the slope in the control ($p=0.39$) but there was for BL2 3.5 mm group ($p=0.0017$) and the BL3 7 mm group ($p=0.0017$).

(iv) RFA-M versus RTQ ANCOVA. Since there was no correlative relationship between RFA-M and RTQ in the control group, these data were omitted from the next step of the analysis. The slopes of the defect group regression lines did not differ significantly ($p=0.68$), and the axis intercepts did differ significantly ($p=0.11$). Therefore, RFA-M and RTQ had the same relationship in the BL2 3.5 mm and BL3 7 mm defect groups.

These results show that there is the same linear relationship between RFA-M and RTQ in the BL2 3.5 mm and BL3 7 mm defect group, but in the control group they show no relationship.

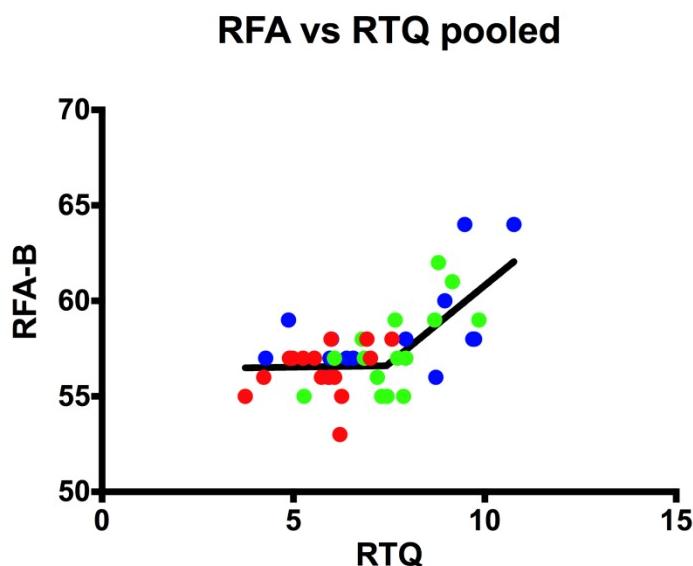
Figure 6. Analysis of RFA relationship to RTQ. A: xy scatter plots of RFA-B versus RTQ for each implant group are shown. **B:** xy scatter plots of RFA-M versus RTQ for each implant group. Lines show linear regression fits to the group data.



(v) RFA-B versus RTQ segmental linear regression. The RFA-B data from each implant group was combined into a pooled dataset, and a segmental linear regression performed (Figure 7). The data gave a moderate Goodness of Fit (R^2 value of 0.4579) to two lines. The first at lower RTQ values had a slope close to zero (0.029), with an intercept on the RFA-B axis of 56.4 units (52.2-60.6 95% confidence interval). The X0 intersection of the lines was at an RTQ value of 7.43 Ncm (6.26-8.60 95% confidence interval).

These results are consistent with RFA-B behaving independently from RTQ at RTQ values below 7.43 Ncm, showing constant value of 56.4 units. At higher RTQ values, RFA-B rises in proportion.

Figure 7. Segmental linear regression of RFA-B versus RTQ.



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